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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/041,950	10/19/2001	Joshua Levy	HEMAC:58774	4919
24201	7590	10/07/2003	EXAMINER	
FULWIDER PATTON LEE & UTECHT, LLP HOWARD HUGHES CENTER 6060 CENTER DRIVE TENTH FLOOR LOS ANGELES, CA 90045			SAUNDERS, DAVID A	
			ART UNIT	PAPER NUMBER
			1644	

DATE MAILED: 10/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

044,950

Applicant(s)

Levy et al

Examiner

SAUNDERS

Group Art Unit

1644

--The MAILING DATE of this communication appears on the cover sheet beneath the correspondence address--

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, such period shall, by default, expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).

### Status

- ☐ Responsive to communication(s) filed on \_\_\_\_\_.
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

### Disposition of Claims

- ☒ Claim(s) 1-37 is/are pending in the application.
- Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1-37 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claim(s) \_\_\_\_\_ are subject to restriction or election requirement.

### Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. § 119 (a)-(d)

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
  - ☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been received.
  - ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
  - ☐ received in this national stage application from the International Bureau (PCT Rule 1.7.2(a)).

\*Certified copies not received: \_\_\_\_\_

### Attachment(s)

- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☒ Notice of Reference(s) Cited, PTO-892
- ☐ Notice of Informal Patent Application, PTO-152
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Other \_\_\_\_\_

Office Action Summary

Claims 1—37 are pending and under examination.

Claims 1-37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1, line 5 “The initial plasma source” lacks antecedent basis because “initial” is not recited at line 3. Likewise, note claim 8, line 2.

Over all, claim 1 is confusing because line 1 refers to “producing... purified immune globulins”, while all recitations from line 13 to the end refer to “the protein”. There is thus no clear nexus between the preamble and the conclusion of the method. It is suggested that, at lines 12-14, applicant recite where the immune globulins are – i.e. in the “liquid” or in the “solid”, and whether or not the proteins in solution include immune globulins.

In claim 1, line 19 “the purified protein” lacks antecedent basis in line 17-18.

At line 20, “the concentrated protein solution” lacks antecedent basis in line 19.

In the last line “the collected protein solution” lacks antecedent basis, note also claim 36, line 1 and claim 37, line 1.

In claims 4 and 5, it is considered that “suspension” should be – suspending – in order to provide consistency with “suspending” recited at line 4.

Claim 7 is grammatically confusing because it is not clear whether it is describing a composition (plasma source) or a step that uses the composition. It

is deemed claim 7 could be recited as – the method of claim 1, wherein the plasma source is derived from a non-human source.

In claim 7, “including...” is indefinite because it is not clear if what follows is or is not part of the invention. It is suggested these embodiments be recited in a new claim depending from 7.

Claims 10 and 11 are confusing because they are inconsistent – i.e. 1M sodium acetate is used in claim 10 and 4M sodium acetate is used in further dependent claim 11.

In claim 12 “for about two hours” lacks antecedent basis because claim 1, line 7 recites “for at least two hours”.

In claim 14, line 3, it is believed that “8M” should be –0.8M—in order to be consistent with specification teachings. Otherwise, the examiner is bewildered as to how addition of a 2.4M-glycine solution to the suspension could result in an 8M-glycine solution.

In claims 16 and 18, line 1 of each, “liquid-separation” lacks antecedent basis because claim 1; line 13 recites “liquid solid separation”.

In claim 21 “the protein is filtered” is confusing because claim <sup>1,</sup><sub>^</sub> line 16 has recited “concentrating...” rather than “filtering...”.

Claim 23 is confusing at lines 2-3 by reciting, “is prepared by a mixture of sodium phosphate...” It is deemed applicant intends to recite an active verb statement, such as – is prepared by mixing sodium phosphate--.

In claim 32 “preferably” is indefinite.

In claim 37, lines 1-2 "the liquid formulation" lacks antecedent basis in claim 36, line 2.

In claim 37 "further comprising the collected protein in the liquid formation<sup>ul</sup>" is confusing. It is suggest applicant recite with an active verb statement such as – wherein the collected protein is a liquid preparation--.

The following references are cited as of interest:

Bertollini et al. (6,093,324) show (Example 4), the resolubilization of a paste of Cohn fractions II and III in Tri-HCl at pH 8.4 or in various sodium acetate buffers, ranging in pH from 4.0 to 5.2. The resolubilized preparation is clarified by filtration and then further purified by anion exchange chromatography through a Macro-Prep HQ column.

Bertollini et al. Also teach that the purified IgG preparation may be treated for viral inactivation (col. 3, lines 8+).

Lebing et al. (6,307,028) teach (cols. 3-4) resolution of a paste of Cohn fraction II and III at pH 3.8-4.5. Sodium caprylate is added to inactivate viruses. The preparation is then filtered and further purified by anion exchange chromatography in two steps.

Mamidi et al. (6,162,904) describe a process of preparing IgG from a paste of Cohn faction II and III. (Example 1). The paste is dissolved in water; sodium acetate is added; the Ph is then adjusted to pH 4.8 by addition of acetate buffer. Cold alcohol is then added to a concentration of 17%. The resulting suspension is then filtered, and the clarified solution is ultrafiltered. A heat

Art Unit: 1644

stabilizer (sorbitol) is added, and the preparation is heat treated to achieve viral inactivation. The resulting preparation is then subjected to two PEG precipitations and the treated with a suspended anion exchange resin (DEAE-Sephadix). The preparation is then chemically treated (with TNBP) to achieve further viral inactivation, and then treated with a suspended cation exchange resin.

Gehring et al. (5,648,472) disclose a method of inactivating viruses in an immunoglobulin preparation by a chemical method using the surfactants TRITON-X100 and/or TNBP. These surfactants are then extracted with a vegetable oil; the oil is then removed by chromatography on a C18 column.

While the above cited references show some steps in common with those recited in the instantly claimed method, none of these alone or in combination suggest the order of steps as instantly recited. Also, none of these references teach the reagents particularly used in the instant claims (e.g. the addition of a solution of about 2.4M glycine in about 7% ethanol).

Claims 1-37 are thus allowable over the prior art of record.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David A. Saunders, Ph.D., whose telephone number is (703) 308-3976. The examiner can normally be reached on Monday-Thursday from 8:00 a.m. to 5:30 p.m. The examiner can also be reached on alternate Fridays.


Application/Control Number: 10/041,950  
Art Unit: 1644

Page 6

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan, can be reached on (703) 308-3973. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

D. Saunders:jmr  
September 30, 2003

  
DAVID SAUNDERS  
PRIMARY EXAMINER  
ART UNIT 182 1644